JUL 2 8 2005

K050808

510(k) SUMMARY – CardioOptics CSA™ System

Applicant Name:
Cardio-Optics, Inc.
2477 55th St. Suite 120
Boulder, Colorado 80301 USA
Phone: (720) 406-1560
Fax: (720) 406-1562

Contact Person:
Larry O. Blankenship
Chief Operating Officer

Date Prepared:
March 29, 2005, Revised July 26, 2005

Device Trade Name:
CardioOptics Coronary Sinus Access (CSA™) System

Classification Name:
Angioscope
Product code LYK, CFR Section 876.1500

Predicate Devices:
Primary Predicate Devices:
Olympus Angioscopes, K911278 & K860858
Product code LYK, CFR Section 876.1500
Additional Predicate Devices:
Biosense Webster CS Deflectable Catheter K955817
Product code DRF, CFR Section 870.1220
St. Jude Medical Apeel™ CS Guide Sheath K031906
Product code DYB, CFR Section 870.1340
Thomas Medical SafeSheath™ CS Sheaths K003731
Product code DYB, CFR Section 870.1340
Acumen Coronary Sinus Visualization System, K042381
Product code DQY, CFR Section 870.1250

Device Description:
The Coronary Sinus Access (CSA™) System provides a catheter and sheath system for providing percutaneous access to the coronary sinus. In addition, the catheter provides visualization to augment the user's ability to locate the coronary sinus for placement of a guide sheath. The system includes a sterile, single use Coronary Sinus Access Kit, which includes a deflecting tip catheter with visualization capability (FLAIR™ CS Catheter), a Guide Sheath Set including a dilator and sheath slitters, and a Sterile Sleeve to drape over the camera pod. The system also includes an Imaging Acquisition System to collect and display video images present in front of the catheter tip.

Intended Use:
The CardioOptics Coronary Sinus Access (CSA™) System is intended to provide subclavian access to the right heart for accessing the coronary sinus and placing a guide sheath suitable for pacemaker lead implantation into the coronary sinus. The system includes visualization means to image anatomical structures to augment navigation.

Device Technological Characteristics and Comparison to Predicate Device(s):	The CSA™ System was shown to be substantially equivalent to percutaneous catheter and guide sheath devices cleared in previous 510(k) submissions. The FLAIR™ CS Catheter with visualization was shown to be substantially equivalent to angioscopes and associated video display systems cleared in previous 510(k) submissions.
Performance Data:	Device testing, including mechanical, functional, and animal, was performed to support substantial equivalence to the predicate devices. Biocompatibility was performed on the blood and tissue contacting materials of the catheter, sheaths, and dilator. The testing was consistent with ISO 10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing." All specified biocompatibility requirements were met. The components of the Coronary Sinus Access Kit will be sterilized using validated Ethylene Oxide (EtO) sterilization processes.
Conclusion:	Based on the data and information presented, the CSA™ System is substantially equivalent to the identified predicate devices in terms of intended use, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2005

Cardio-Optics
c/o Mr.Larry Blankenship
Chief Operating Officer
2477 55th Street, Ste. 120
Boulder, CO 80301

Re: K050808
Trade/ Name: Coronary Sinus Access System
Regulation Number: 21 CFR 876.1500
Regulation Name: Angioscope
Regulatory Class: Class II (two)
Product Code: LYK
Dated: July 19, 2005
Received: July 20, 2005

Dear Mr. Blankenship:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

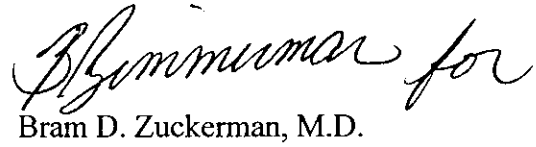
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K050808

Device Name: CardioOptics Coronary Sinus Access (CSA™) System

Indications for Use:

The CardioOptics Coronary Sinus Access (CSA™) System is intended to provide subclavian access to the right heart for accessing the coronary sinus and placing a guide sheath suitable for pacemaker lead implantation into the coronary sinus. The system includes visualization means to image anatomical structures to augment navigation.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050808